

**K130456 WUNDER PREGNANCY TEST**Apr 8, 2014  
410 days to decisionK130456 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k130456/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Feb 22, 2013
Decision date	Apr 8, 2014
Days to decision	410 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>James Nguyen</b>
Location	San Jose, CA, US
Contact	JAMES NGUYEN, M.D.
510(k) history	1 submissions · 1 cleared · 2014-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130456/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 7, 2026